



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

October 17, 2002

WARNING LETTER
CHI-27-02

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

937058

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Madeline Y. Giliana
Partner and Co-Owner
Giliana & Huziran dba Clark Bakery
5140 N. Clark Street
Chicago, IL 60640

Dear Ms. Giliana:

The Food and Drug Administration (FDA) conducted an inspection of your firm on July 9, 2002, and found serious deviations from the Federal Food, Drug, and Cosmetic Act (the Act), as well as from Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), Food Labeling. These deviations cause the Pita Bread and the Assyrian Samoon Bread that you manufacture to be in violation of Sections 403(i)(1), 403(i)(2), and 403(q)(1) of the Act. You can find this Act and the applicable regulations through links on FDA's home page at www.fda.gov.

Our determinations, in regard to the deviations we found during the current inspection, are as follows:

- › Both your Pita Bread and your Assyrian Samoon Bread products are misbranded under section 403(i)(1) of the Act because the statement of identity you use for both breads, "Assyrian Samoon and Pita Bread," fails to clearly identify the common or usual name of the bread that is actually contained in the package.
- › Your Pita Bread product is misbranded within the meaning of section 403(i)(2) of the Act because the label does not list wheat gluten in the ingredient statement. Wheat gluten is an ingredient in the recipe your firm uses to manufacture Pita Bread. The declaration of wheat gluten is of particular concern to individuals who have a gluten intolerance.

- › Both your Pita Bread and your Assyrian Samoon Bread are further misbranded in that they fail to bear a label with nutritional information, as required under Section 403(q)(1) of the Act, and 21 CFR §101.9. Some small businesses are exempt from the nutritional labeling requirements; however, it is your responsibility to determine if your firm meets exemption requirements and to file an exemption notice.

The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence to each requirement of the Act, and its implementing regulations, including being vigilant that products you manufacture and distribute meet all of the applicable statutory and regulatory requirements. We request that you take prompt action to correct all violations. Failure to promptly correct these violations may result in regulatory action without further notice, including seizure and/or injunction.

Please provide this office, within 15 working days of receipt of this letter, a detailed response in writing that states the actions you plan to take, or have taken, to correct and prevent the objectionable conditions we have cited. Provide the specific time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation (e.g., modified label exhibits) to show that corrections have been made.

Your reply should be directed to James T. Karpus, Compliance Officer, at the address listed in the letterhead.

Sincerely,

\s\

Arlyn H. Baumgarten
District Director

cc: Mr. Bakida Huziran, Co-Owner
Giliana & Huziran dba Clark Bakery
5140 N. Clark Street
Chicago, IL 60640